REMARKS

In the Office Action dated February 12, 2007, the Examiner has made the Restriction Requirement final, and has withdrawn claims 2-4, 6-8 and 16-82 from consideration. The Examiner has examined and rejected claims 1, 5 and 9-15. The Examiner has also objected to the specification for certain alleged informalities. In addition, the Examiner has objected to Applicants' claim of priority from PCT/AU02/01258.

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

In the Action, the Examiner has objected to the specification for containing an embedded hyperlink, for example, on page 99, line 23. The hyperlink refers to a web site where the Blast Program can be found. Applicants have deleted the hyperlink. As such, the objection to the specification is overcome and withdrawal thereof is respectfully requested.

The Examiner has also objected to Applicant's claim of priority. The present application was filed as a continuation of PCT/AU02/01258, having an international filing date of September 13, 2002 and claiming priority from U.S. Provisional application 60/322,288, filed on September 14, 2001. The Examiner alleges that SEQ ID NO: 7 of the instant application and SEQ ID NO: 7 of PCT/AU02/01258 differ by a nucleotide. Specifically, as further set forth in the Action (on page 14, last paragraph), the Examiner indicates that the nucleotide at position 3362 is "T" in PCT/AU02/01258, but is "R" in the present application. Further, the Examiner alleges that the sequence of SEQ ID NO: 7 is not disclosed in the '288 application. Therefore, the Examiner concludes that the effective filing date (with respect to SEQ ID NO: 7) is the filing

date of the instant application (i.e., March 12, 2004).

Applicants respectfully submit that the present application was filed as a continuation application of PCT/AU02/01258. The specification of the present application, including the Sequence Listing, is identical with that of PCT/AU02/01258. Contrary to the Examiner's allegation, the nucleotide at position # 3362 of SEQ ID NO: 7 is clearly "R" in PCT/AU02/01258 as published, which is the same as the present application. In any event, Applicants respectfully submit that the present application is entitled to the benefit of the filing date of PCT/AU02/01258, i.e., September 13, 2002.

Turning to the claims, the Examiner has alleged that Applicants previously elected, with traverse, Group I, claims 1-24 and SEQ ID NO: 7. The Examiner states that Applicants' arguments in response to the Restriction Requirement have been considered but are not persuasive, and therefore the Examiner has made the Restriction Requirement final and has withdrawn claims 2-4, 6-8 and 16-82 from consideration.

Applicants respectfully disagree with the Examiner's determination of the claims that should be withdrawn from consideration. The Examiner's attention is respectfully directed to the grouping of the claims set forth in the Restriction Requirement. Group I includes claims 1-33. Contrary to the Examiner's allegation, Applicants elected Group I, claims 1-33 and SEQ ID NO: 7, rather than claims 1-24.

Applicants further submit that claim 16 specifically recites SEQ ID NO: 7. In fact, SEQ ID NO: 7 was added to claim 16 in the Applicants' Amendment dated January 12, 2007 pursuant to the Examiner's specific suggestion made during a telephone interview with the undersigned attorney on January 8, 2007. Therefore, claim 16 should be included in the

examination, at least to the extent that the subject matter of the claim reads on SEQ ID NO: 7. In other words, the method of claim 16 should be examined to the extent that co-expression of two or more nucleic acid molecules are being detected, wherein said two or more nucleic acids include a nucleic acid molecule comprising SEQ ID NO: 7. In this connection, Applicants have amended claim 16 to define that said two or more nucleic acids include a nucleic acid molecule comprising SEQ ID NO: 7.

Moreover, claims 19-28 all depend on claim 16 and all specifically recite SEQ ID NO: 7. These claims are directed to methods where the co-expression of a combination of sequences is being detected. The combinations in all of claims 19-28 as presently recited include SEQ ID NO: 7. Therefore, Applicants respectfully submit that claims 19-28 should also be included in the examination. Applicants further respectfully direct the Examiner's attention to MPEP 803.04, where it is stated that the presence of one novel and unobvious sequence within a combination renders the entire combination allowable.

Finally, Claims 29-33, although not specifically reciting SEQ ID NO: 7, ultimately depend from claims 1 and/or 16. Therefore, these claims should also be included in the examination.

In view of the foregoing, Applicants respectfully submit that the Examiner's determination that claims 16 and 19-33 are withdrawn from consideration is in error. Although the status indicators of these claims are identified as "withdrawn" in this response, reconsideration and examination of these claims are respectfully requested.

Claims 1, 5 and 9-15 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Essentially, the Examiner is of the

opinion that the specification fails to describe the common attributes and characteristics of SEQ ID NO: 7-related sequences in all organisms, such as other sequences in human or neoplasm markers in non-human subjects. The Examiner also contends that the specification does not provide guidance to a structure/function relationship that would facilitate the determination as to whether a nucleic acid would be a useful neoplasm marker. Therefore, the Examiner contends that the specification has not conveyed to those skilled in the art that the applicant was in possession of the claimed genus at the time the application was filed.

In an effort to favorably advance prosecution of the present application, Applicants have deleted references to "functional derivative, variant or homologue". In addition, Applicants have amended the claims to require hybridization conditions to be "high" stringency conditions. Thus, the nucleic acids that are related (i.e., homologous) to SEQ ID NO: 7, are now structurally defined by their hybridization characteristics. That is, the high stringency hybridization conditions dictate that these nucleic acids are structurally related, or bear structural similarity, to SEQ ID NO: 7. In light of the amendments to the claims and the disclosure in the specification, Applicants respectfully submit that the subject matter, as presently claimed, is adequately described in the application in compliance with the written description requirement under 35 U.S.C. §112, first paragraph. Accordingly, withdrawal of the rejection is therefore respectfully requested.

Claims 1, 5 and 9-15 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner has acknowledged that the specification is enabling for determining the overexpression of SEQ ID NO: 7 in an individual in a colorectal biopsy sample as an indication of colorectal adenoma. However, the Examiner

contends that the specification does not reasonably provide enablement for detection of overexpression of any other SEQ ID NO: 7 related sequences in any other types of adenoma in any other samples in other non-human individuals, as an indication of the onset or predisposition to the onset of neoplasm.

As submitted above, Applicants have deleted references to "functional derivative, variant or homologue". In addition, Applicants have amended the claims to require hybridization conditions to be "high" stringency conditions. In an effort to further advance prosecution, Applicants have also amended the claims to further define the neoplasm as a gastrointestinal tract neoplasm.

Applicants respectfully submit that those skilled in the art would be able to practice the claimed methods, as presently recited, without undue experimentation. In particular, as the Examiner has acknowledged, the specification describes the determination of an overexpression of SEQ ID NO: 7 in an individual in a colorectal biopsy sample as an indication of colorectal adenoma. In light of this disclosure, those skilled in the art would be able to determine nucleic acids that are structurally related to SEQ ID NO: 7 and their overexpression in order to diagnose a gastrointestinal tract neoplasm.

In terms of the samples which are analyzed in the context of the methods of the present invention, Applicants respectfully submit that once provided with the recognition that SEQ ID NO: 7 is upregulated in the context of gastrointestinal tract neoplasms, those skilled in the art would be able to determine, without undue experimentation, a suitable cellular source for use in the determination, whether it be a biopsy sample, sloughed of cells, stool samples or protein products which have been secreted into the blood. Provided that the test result is

compared to a control sample, an increase in the expression of SEQ ID NO: 7 is indicative of a gastrointestinal tract neoplasm.

In view of the foregoing, Applicants respectfully submit that the subject matter as presently claimed, is fully enabled. Applicants also possess additional data that further support enablement of the present invention, and if necessary, Applicants are willing to submit such additional supporting information. Applicants respectfully submit that the enablement rejection under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 1, 5, and 9-15 are rejected under 35 U.S.C. §102(a) and (e) as allegedly anticipated by James et al. (PCT/AU020/1258).

Apparently the Examiner's rejection is premised on the Examiner's determination that the present application is not entitled to the priority of PCT/AU02/01258, because the Examiner has erroneously determined that the nucleotide at position # 3362 is "T" in PCT/AU02/01258, but is "R" in the present application. Therefore, the Examiner has applied PCT/AU02/01258 as prior art against the present claims.

The Examiner indicates in the Action that a sequence alignment is provided to show the difference between SEQ ID NO: 7 of the present application and that of PCT/AU02/01258. However, Applicants have not found any attachment of any sequence alignment to the Office Action. As submitted above, the present application was filed as a continuation application of PCT/AU02/01258. The specification of the present application, including the Sequence Listing, is identical with that of PCT/AU02/01258. Contrary to the Examiner's allegation, the nucleotide at position # 3362 of SEQ ID NO: 7 is clearly "R" in PCT/AU02/01258 as published, which is

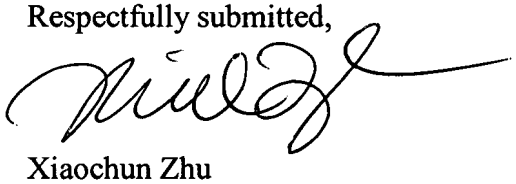
the same as the present application. Therefore, Applicants respectfully submit that the Examiner's determination of any sequence difference is in error. As such, withdrawal of the rejections based on PCT/AU020/1258 is respectfully requested.

Claims 1 and 9-13 are rejected under 35 U.S.C. §102(b) as anticipated by Loiseau (*Neuroscience Letter* 263: 173-176, 1999). Loiseau teaches a method of detecting p73 gene transcripts. The rejection is apparently based on an interpretation of claim 1 by the Examiner to broadly encompass a p73 gene transcript as a sequence variant of SEQ ID NO: 7.

Applicants respectfully submit that the claims as amended do not recite "functional derivative, variant or homologue". The Examiner has not established that a p73 gene transcript would hybridize to SEQ ID NO: 7 under high stringency conditions as required by the claims. It is believed, therefore, that the anticipation rejection based on Loiseau is overcome, and withdrawal thereof is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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